



DEPARTMENT OF HEALTH AND HUMAN SERVICES

g 4083d
Food and Drug Administration
Atlanta District Office

60 8th Street, N.E.
Atlanta, Georgia 30309

May 22, 2003

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Brenda L. Davis., President
Washington Crab & Seafood Co., LLC
P.O. Box 2185
Washington, NC 27889

Warning Letter
03-ATL-20

Dear Ms. Davis:

On April 9-10, 2003, an investigator from the Food and Drug Administration (FDA), Billy M. Battles, conducted an inspection of your seafood repacking facility located at 321 Pierce Street, Washington, North Carolina. During that inspection, our investigator documented serious deviations from the Seafood HACCP regulations, Title 21, Code of Federal Regulations, Part 123 (21 CFR Part 123). In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of this part, renders the fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act), 21 U.S.C. § 342(a)(4). Accordingly, your fresh, histamine fish, and refrigerated pasteurized crabmeat has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. You may find the Act and the Seafood HACCP regulations through links in FDA's home page at www.fda.gov.

The deviations of concern are as follows:

You must implement the record keeping system that you listed in your HACCP plan to comply with 21 CFR 123.6(b). However, your firm did not record monitoring observations at the receiving critical control point (CCP) to control the histamine hazard listed in your HACCP plan for histamine prone fish received from another processor. Our investigator identified several shipments of histamine prone fish received by your firm in March and April 2003, for which there were no records of the internal temperature of the incoming fish or the adequacy of ice on said fish.

In addition, our investigator also documented numerous shipments of histamine prone fish received by your firm from fishermen during the period of November 2002 and

March 2003, for which the records for monitoring observations at the receiving step were either missing or incomplete.

Also, your firm failed to record monitoring observations at the receiving CCP to control the pathogen growth and toxin formation hazard listed in your plan for refrigerated pasteurized crabmeat received from other processors. Our investigator documented two separate shipments of pasteurized crabmeat received by your firm on April 2003, for which there were no records of the adequacy of ice on the crabmeat containers or of the product temperature of the incoming crabmeat.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

Please respond in writing within 15 working days from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You should include in your response documentation such as copies of HACCP plans, and HACCP monitoring records, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations, and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Please send your reply to Carlos A. Bonnin, Compliance Officer, U.S. Food and Drug Administration, 60 Eighth Street, N.E., Atlanta, Georgia 30309. If you have questions regarding any issue in this letter, please contact Mr. Bonnin at 404-253-1277.

Sincerely,



Mary H. Woleske, Director
Atlanta District

cc: Jesse T. Tripp, Jr., Vice President
Washington Crab & Seafood Co, LLC
P.O. Box 2185
Washington, NC 27889